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10/797,616

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Richard W. Gross

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EXAMINER

MOSS, KERI A

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

08/04/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/797,616 | Applicant(s) GROSS ET AL. | |
| | Examiner KERI A. MOSS | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008 and 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 19-54 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Non-Final Rejection is intended to replace the Non-Final Rejection mailed on July 9, 2008.

Election/Restrictions

2. Applicant's election with traverse of Group I claims 1-17, 55 and 18 in the reply filed on April 17, 2008 is acknowledged. The traversal is on the ground(s) that the groups are related and that it would not be a serious burden on the examiner. This is not found persuasive because the different groups are located in different classes and subclasses and each group would require a different search. In addition, the non-elected inventions relate to either administration of a drug or testing with different drugs, which involves independent and distinct subject matter to the analysis in claim 1. Thus, the non-elected inventions would require an undue examination burden.

The requirement is still deemed proper and is therefore made FINAL.

Response to Amendment

3. The previous rejections under 35 USC 112, 2nd paragraph have been withdrawn in light of applicants' amendments and arguments. New grounds for rejection under 35 USC 112, 1st paragraph have been added.

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4. With the exception of claim 18, the previous rejections under 35 USC 103 under Han et al in view of Koivusalo have been withdrawn in light of applicants' amendments and arguments.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims **1-18 and 55** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cellular lipid individual molecular species, does not reasonably provide enablement for any lipid individual molecular species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The examples in the specification are all cellular lipids. Given the unpredictable nature of chemical reactions, it would require undue experimentation to make and use this invention with non-cellular lipid individual molecular species.

Applicant expressly claims using a biological sample, thus the word "cellular" would add clarity and consistency to the claims. To overcome this rejection, the examiner recommends inserting the word "cellular" into the preambles of claims 1 and 8 immediately preceding "lipid individual molecular species."

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claim **18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Han et al. (Proc. Natl. Acad. Sci. USA, 1994) or Brugger et al. (Proc. Natl. Acad. Sci., USA, 1997) in view of Koivusalo et al. (J. Lipid Res., 2001).

Han discloses "electrospray ionization mass spectroscopic analysis of human erythrocyte plasma membrane phospholipids" involving linear regression analysis for correcting different instrumental efficiencies for molecular species.

Bragger teaches "quantitative analysis of biological membrane lipids at the low picomole level by nano-electrospray ionization tandem mass spectrometry", including ESI-MS/MS tandem spectrometry performed directly on extracts. Calibration functions are applied as described on page 2343, right column and Figure 7.

While Han and Bragger do not specifically disclose analysis of triglycerides, triglycerides are closely related to phospholipids of cell membranes. Han and Bragger do not specifically teach applying non-linear regression analysis for determining correlation functions for correcting efficiencies (sensitivities) of different molecular species.

Koivusalo teaches "quantitative determination of phospholipid compositions by ESI-MS: effects of acyl chain length, unsaturation, and lipid concentration on instrument response [species sensitivities, Ex.]" (Title). Koivusalo indicates that linearity of the instrument response can vary depending on the phospholipids acyl chain length, and

linear correction function was applied for low total lipid concentrations, and at high total lipid concentrations the exponential (non-linear) regression function was indicated as better fitting the instrument response (see page 664, right column).

Therefore, it would have been obvious for any person of ordinary skill in the art to modify Han or Brugger's method using Koivusalo's results for non-linear response of ESI-MS instrument to lipids in high concentrations, for which non-linear regression fitting should be employed, because Han, Brugger and Koivusalo use analogous instruments and analytes.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims **1-18 and 55** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 7,306,952. Although the conflicting claims are not identical, they are not patentably distinct from each other because the language of the claims differs only in the preamble of the independent claims as the claims of the '952 patent, wherein the '952 patent claims are for the determination of triglyceride, and the instant application claims are for the determination of lipid individual molecular species. The species "triglyceride" anticipates the genus "lipid individual molecular species."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

/Keri A. Moss/
Examiner, Art Unit 1797